Complete Summary

GUIDELINE TITLE

Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis.

BIBLIOGRAPHIC SOURCE(S)

Panlilio AL, Cardo DM, Grohskopf LA, Heneine W, Ross CS. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. MMWR Recomm Rep 2005 Sep 30;54(RR-9):1-17. PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline is a partial update of a previous guideline: <u>Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis</u>. MMWR Recomm Rep 2001 Jun 29;50(RR-11):1-52. The recommendations contained in the 2005 version of this guideline update recommendations pertaining to the management of occupational HIV exposure. Recommendations for the management of occupational exposure to hepatitis B and hepatitis C viruses contained in the previous guideline are still considered to be current.

Additional status information regarding this guideline is available from the <u>AIDSinfo Web site</u>, telephone (800) 448-0440, fax (301) 519-6616; TTY (888) 480-3739.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references drugs for which important revised regulatory and/or warning information has been released.

On June 10, 2005, Bristol-Myers Squibb and FDA notified healthcare professionals of revisions to the WARNINGS, PRECAUTIONS/Pregnancy and Information for Patients, and PATIENT INFORMATION sections of the prescribing information for Sustiva (efavirenz), indicated in the treatment of HIV-1 infection. The revisions are a result of four retrospective reports of neural tube defects in infants born to women with first trimester exposure to Sustiva, including three cases of meningomyelocele and one Dandy Walker Syndrome. As Sustiva may cause fetal harm when administered during the

- first trimester to a pregnant woman, pregnancy should be avoided in women receiving Sustiva. An antiretroviral pregnancy registry has been established to monitor fetal outcomes of pregnant women exposed to Sustiva. See the <u>FDA</u> Web site for more information.
- On January 19, 2005, the U.S. Food and Drug Administration (FDA) issued a public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine. The Indications and Usage section now recommends against starting nevirapine treatment in women with CD4+cell counts greater than 250 cells/mm3 unless benefits clearly outweigh risks. This recommendation is based on a higher observed risk of serious liver toxicity in patients with higher CD4 cell counts prior to initiation of therapy. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV) infection

GUIDELINE CATEGORY

Evaluation Prevention

CLINICAL SPECIALTY

Family Practice Infectious Diseases Internal Medicine Preventive Medicine

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Hospitals Nurses Physician Assistants Physicians Public Health Departments

GUIDELINE OBJECTIVE(S)

To update United States Public Health Service (PHS) recommendations for the management of health-care personnel (HCP) who have occupational exposure to blood and other body fluids that might contain human immunodeficiency virus (HIV)

TARGET POPULATION

Health care personnel who have occupational exposure to blood and other body fluids that may contain human immunodeficiency virus (HIV)

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Evaluation of exposure site, risk associated with exposure, exposure source (including rapid human immunodeficiency virus [HIV] testing of source), and exposed person
- 2. Post-exposure prophylaxis (PEP), where exposure poses risk of infection
- 3. Consultation with persons with expertise in antiretroviral therapy and HIV transmission, as indicated
- 4. Follow-up testing, monitoring of PEP toxicity, and counseling

MAJOR OUTCOMES CONSIDERED

- Risk of occupational transmission of human immunodeficiency virus (HIV)
- Effectiveness of HIV post-exposure prophylaxis regimens
- Side effects and adverse events associated with medications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVI DENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse: This guideline is a partial update to a previous Centers for Disease Control and Prevention (CDC) guideline, "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis," released June 29, 2001. The recommendations for management of occupational exposure to hepatitis B and C are still current and can be found on the NGC Web site.

This report updates U.S. Public Health Service (PHS) recommendations for the management of health-care personnel (HCP) who have occupational exposure to

blood and other body fluids that might contain human immunodeficiency virus (HIV). Although the principles of exposure management remain unchanged, recommendations for HIV postexposure prophylaxis (PEP) regimens have been changed. This report emphasizes adherence to PEP when it is indicated for an exposure, expert consultation in management of exposures, follow-up of exposed workers to improve adherence to PEP, and monitoring for adverse events, including seroconversion. To ensure timely postexposure management and administration of HIV PEP, clinicians should consider occupational exposures as urgent medical concerns.

Recommendations for the Management of HCP Potentially Exposed to HIV

Exposure prevention remains the primary strategy for reducing occupational bloodborne pathogen infections. However, occupational exposures will continue to occur, and PEP will remain an important element of exposure management.

HIV PEP

The recommendations provided in this report (see tables below and Appendix in the original guideline document) apply to situations in which HCP have been exposed to a source person who either has or is considered likely to have HIV infection. These recommendations are based on the risk for HIV infection after different types of exposure and on limited data regarding efficacy and toxicity of PEP. If PEP is offered and taken and the source is later determined to be HIVnegative, PEP should be discontinued. Although concerns have been expressed regarding HIV-negative sources being in the window period for seroconversion, no case of transmission involving an exposure source during the window period has been reported in the United States. Rapid HIV testing of source patients can facilitate making timely decisions regarding use of HIV PEP after occupational exposures to sources of unknown HIV status. Because the majority of occupational HIV exposures do not result in transmission of HIV, potential toxicity must be considered when prescribing PEP. Because of the complexity of selecting HIV PEP regimens, when possible, these recommendations should be implemented in consultation with persons having expertise in antiretroviral therapy and HIV transmission. Reevaluation of exposed HCP should be strongly encouraged within 72 hours postexposure, especially as additional information about the exposure or source person becomes available.

Timing and Duration of PEP

PEP should be initiated as soon as possible, preferably within hours rather than days of exposure. If a question exists concerning which antiretroviral drugs to use, or whether to use a basic or expanded regimen, the basic regimen should be started immediately rather than delay PEP administration. The optimal duration of PEP is unknown. Because 4 weeks of zidovudine (ZDV) appeared protective in occupational and animal studies, PEP should be administered for 4 weeks, if tolerated.

Recommendations for the Selection of Drugs for HIV PEP

The selection of a drug regimen for HIV PEP must balance the risk for infection against the potential toxicities of the agent(s) used. Because PEP is potentially

toxic, its use is not justified for exposures that pose a negligible risk for transmission (see tables below). The initial HIV PEP regimens recommended in these guidelines should be viewed as suggestions that can be changed if additional information is obtained concerning the source of the occupational exposure (e.g., possible treatment history or antiretroviral drug resistance) or if expert consultation is provided. Given the complexity of choosing and administering HIV PEP, whenever possible, consultation with an infectious diseases consultant or another physician who has experience with antiretroviral agents is recommended, but it should not delay timely initiation of PEP.

Consideration should be given to the comparative risk represented by the exposure and information regarding the exposure source, including history of and response to antiretroviral therapy based on clinical response, CD4+ T-cell counts, viral load measurements, and current disease stage. When the source person's virus is known or suspected to be resistant to one or more of the drugs considered for the PEP regimen, the selection of drugs to which the source person's virus is unlikely to be resistant is recommended; expert consultation is advised. If this information is not immediately available, initiation of PEP, if indicated, should not be delayed; changes in the regimen can be made after PEP has started, as appropriate. For HCP who initiate PEP, re-evaluation of the exposed person should occur within 72 hours postexposure, especially if additional information about the exposure or source person becomes available.

PHS continues to recommend stratification of HIV PEP regimens based on the severity of exposure and other considerations (e.g., concern for antiretroviral drug resistance in the exposure source). The majority of HIV exposures will warrant a two-drug regimen, using two nucleoside reverse transcriptase inhibitors (NRTIs) or one NRTI and one nucleotide analogue reverse transcriptase inhibitor (NtRTI) (see tables below and the Appendix to the original guideline document). Combinations that can be considered for PEP include ZDV and lamivudine (3TC) or emtricitabine (FTC); stavudine (d4T) and 3TC or FTC; and tenofovir (TDF) and 3TC or FTC. In the previous PHS guidelines, a combination of d4T and didanosine (ddI) was considered one of the first-choice PEP regimens; however, this regimen is no longer recommended because of concerns about toxicity (especially neuropathy and pancreatitis) and the availability of more tolerable alternative regimens.

Table. Recommended HIV PEP for Percutaneous Injuries

	Infection Status of Source				
Exposure	HIV-	HIV-	Source of	Unknown	HIV-
Type	positive,	positive,	Unknown HIV	Source ^c	negative
	Class 1 ^a	Class 2ª	Status ^b		
Less	Recommend	Recommend	Generally, no	Generally, no PEP	No PEP
severed	basic 2-drug	expanded	PEP warranted;	warranted;	warranted
	PEP	>3-drug PEP		however, consider	
				basic 2-drug PEP ^e	
				in settings in	
				which exposure to	
				HIV-infected	
				persons is likely	
More	Recommend	Recommend	Generally, no	Generally, no PEP	No PEP

	Infection Status of Source				
Exposure	HIV-	HIV-	Source of	Unknown	HIV-
Type	positive,	positive,	Unknown HIV	Source ^c	negative
	Class 1 ^a	Class 2 ^a	Status ^b		
severe ^g	expanded 3-	expanded	PEP warranted;	warranted;	warranted
	drug PEP	>3-drug PEP		however, consider	
			consider basic	basic 2-drug PEP ^e	
			2-drug PEP ^e for	in settings in	
			source with HIV	which exposure to	
			risk factors ^f	HIV-infected	
				persons is likely	

^a HIV-positive, class 1--Asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL). HIV-positive, class 2--Symptomatic HIV infection, acquired immunodeficiency syndrome, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up for all exposures.</p>

Table. Recommended HIV PEP for Mucous Membrane Exposures and Nonintact Skin^a Exposures

	Infection Status of Source				
Exposure	HIV-	HIV-	Source of	Unknown	HIV-
Туре	positive,	positive,	Unknown HIV	Sourced	negative
	Class 1 ^b	Class 2 ^b	Status ^c		
Small	Consider	Recommend	Generally, no	Generally, no PEP	No PEP
	basic 2-drug PEP ^f	basic 2-drug PEP	PEP warranted ⁹	warranted	warranted
Large	Recommend	Recommend	Generally, no	Generally, no PEP	No PEP
volume ^h	basic 2-drug	expanded	PEP warranted;	warranted;	warranted
	PEP	>3-drug PEP	however,	however, consider	

^b For example, deceased source person with no samples available for HIV testing

^c For example, a needle from a sharps disposal container

^d For example, solid needle or superficial injury

^e The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.

^f If PEP is offered and administered and the source is later determined to HIV-negative, PEP should be discontinued.

⁹ For example, large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein

	Infection Status of Source				
Exposure	HIV-	HIV-	Source of	Unknown	HIV-
Type	positive,	positive,	Unknown HIV	Sourced	negative
	Class 1 ^b	Class 2 ^b	Status ^c		
			consider basic	basic 2-drug PEP ^f	
			2-drug PEP ^f for	in settings in	
			source with HIV	which exposure to	
			risk factors ^g	HIV-infected	
				persons is likely	

^a For skin exposures, follow-up is indicated only if evidence exists of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).

The addition of a third (or even a fourth) drug should be considered for exposures that pose an increased risk for transmission or that involve a source in whom antiretroviral drug resistance is likely. The addition of a third drug for PEP after a high-risk exposure is based on demonstrated effectiveness in reducing viral burden in HIV-infected persons. However, no definitive data exist that demonstrate increased efficacy of three- compared with two-drug HIV PEP regimens. Previously, indinavir (IDV), nelfinavir (NFV), efavirenz (EFV), or abacavir (ABC) were recommended as first-choice agents for inclusion in an expanded PEP regimen.

PHS now recommends that expanded PEP regimens be protease inhibitor (PI)-based. The PI preferred for use in expanded PEP regimens is lopinavir/ritonavir (LPV/RTV). Other PIs acceptable for use in expanded PEP regimens include atazanavir, fosamprenavir, RTV-boosted IDV, RTV-boosted saquinavir (SQV), or

^b HIV-positive, class 1--Asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL). HIV-positive, class 2--Symptomatic HIV infection, acquired immunodeficiency syndrome, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up for all exposures.

^c For example, deceased source person with no samples available for HIV testing

^d For example, a splash from inappropriately disposed blood

^e For example, a few drops

^f The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.

⁹ If PEP is offered and administered and the source is later determined to HIV-negative, PEP should be discontinued.

^h For example, a major blood splash

NFV (see Appendix to the original guideline document). Although side effects are common with nonnucleoside reverse transcriptase inhibitors (NNRTIs), EFV may be considered for expanded PEP regimens, especially when resistance to PIs in the source person's virus is known or suspected. Caution is advised when EFV is used in women of childbearing age because of the risk of teratogenicity.

Drugs that may be considered as alternatives to the expanded regimens, with warnings about side effects and other adverse events, are EFV or PIs as noted in the Appendix to the original guideline document in combination with ddI and either 3TC or FTC. The fusion inhibitor enfuvirtide (T20) has theoretic benefits for use in PEP because its activity occurs before viral-host cell integration; however, it is not recommended for routine HIV PEP because of the mode of administration (subcutaneous injection twice daily). Furthermore, use of T20 has the potential for production of anti-T20 antibodies that cross react with HIV gp41. This could result in a false-positive, enzyme immunoassay (EIA) HIV antibody test among HIV-uninfected patients. A confirmatory Western blot test would be expected to be negative in such cases. T20 should only be used with expert consultation.

Antiviral drugs not recommended for use as PEP, primarily because of the higher risk for potentially serious or life-threatening adverse events, include ABC, delavirdine, zalcitabine (ddC), and, as noted previously, the combination of ddl and d4T. Nevirapine (NVP) should not be included in PEP regimens except with expert consultation because of serious reported side effects, including hepatotoxicity (with one instance of fulminant liver failure requiring liver transplantation), rhabdomyolysis, and hypersensitivity syndrome.

Because of the complexity of selection of HIV PEP regimens, consultation with persons having expertise in antiretroviral therapy and HIV transmission is strongly recommended. Certain institutions have required consultation with a hospital epidemiologist or infectious diseases consultant when HIV PEP use is under consideration. This can be especially important in management of a pregnant or breastfeeding worker or a worker who has been exposed to a heavily treatment-experienced source (see below).

Situations for Which Expert Consultation* for HIV PEP Is Advised

- Delayed (i.e., later than 24-36 hours) exposure report
 - Interval after which lack of benefit from PEP undefined
- Unknown source (e.g., needle in sharps disposal container or laundry)
 - Use of PEP to be decided on case-by-case basis
 - Consider severity of exposure and epidemiologic likelihood of HIV exposure.
 - Do not test needles or other sharp instruments for HIV.
- Known or suspected pregnancy in the exposed person
 - Use of optimal PEP regimens not precluded
 - PEP not denied solely on basis of pregnancy
- Breastfeeding in the exposed person
 - Use of optimal PEP regimens not precluded
 - PEP not denied solely on basis of breastfeeding
- Resistance of the source virus to antiretroviral agents
 - Influence of drug resistance on transmission risk unknown

- If source person's virus is known or suspected to be resistant to one or more of the drugs considered for PEP, selection of drugs to which the source person's virus is unlikely to be resistant recommended
- Resistance testing of the source person's virus at the time of the exposure not recommended
- Initiation of PEP not to be delayed while awaiting any results of resistance testing
- Toxicity of the initial PEP regimen
 - Adverse symptoms (e.g., nausea and diarrhea) common with PEP
 - Symptoms often manageable without changing PEP regimen by prescribing antimotility or antiemetic agents
 - In other situations, modifying the dose interval (i.e., taking drugs after meals or administering a lower dose of drug more frequently throughout the day, as recommended by the manufacturer) might help alleviate symptoms when they occur.

• Resources for consultation are listed in the original guideline document.

Follow-Up of Exposed HCP

Postexposure Testing

HCP with occupational exposure to HIV should receive follow-up counseling, postexposure testing, and medical evaluation regardless of whether they receive PEP. HIV-antibody testing by enzyme immunoassay should be used to monitor HCP for seroconversion for >6 months after occupational HIV exposure. After baseline testing at the time of exposure, follow-up testing could be performed at 6 weeks, 12 weeks, and 6 months after exposure. Extended HIV follow-up (e.g., for 12 months) is recommended for HCP who become infected with hepatitis C virus (HCV) after exposure to a source coinfected with HIV and HCV. Whether extended follow-up is indicated in other circumstances (e.g., exposure to a source coinfected with HIV and HCV in the absence of HCV seroconversion or for exposed persons with a medical history suggesting an impaired ability to mount an antibody response to acute infection) is unclear. Although rare instances of delayed HIV seroconversion have been reported, the infrequency of this occurrence does not warrant adding to exposed persons' anxiety by routinely extending the duration of postexposure follow-up. However, this should not preclude a decision to extend follow-up in a particular situation based on the clinical judgment of the exposed person's health-care provider. The routine use of direct virus assays (e.g., HIV p24 antigen EIA or tests for HIV ribonucleic acid) to detect infection among exposed HCP usually is not recommended. Despite the ability of direct virus assays to detect HIV infection a few days earlier than EIA, the infrequency of occupational seroconversion and increased costs of these tests do not warrant their routine use in this setting. In addition, the relatively high rate of false-positive results of these tests in this setting could lead to unnecessary anxiety or treatment. Nevertheless, HIV testing should be performed on any exposed person who has an illness compatible with an acute retroviral syndrome, regardless of the interval since exposure. A person in whom HIV infection is identified should be referred for medical management to a specialist with

^{*}Either with local experts or by contacting the National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline), telephone 888-448-4911.

expertise in HIV treatment and counseling. Health-care providers caring for persons with occupationally acquired HIV infection can report these cases to the CDC at telephone 800-893-0485 or to their state health departments.

Monitoring and Management of PEP Toxicity

If PEP is used, HCP should be monitored for drug toxicity by testing at baseline and again 2 weeks after starting PEP. The scope of testing should be based on medical conditions in the exposed person and the toxicity of drugs included in the PEP regimen. Minimally, laboratory monitoring for toxicity should include a complete blood count and renal and hepatic function tests. Monitoring for evidence of hyperglycemia should be included for HCP whose regimens include any PI; if the exposed person is receiving IDV, monitoring for crystalluria, hematuria, hemolytic anemia, and hepatitis also should be included. If toxicity is noted, modification of the regimen should be considered after expert consultation; further diagnostic studies might be indicated.

Exposed HCP who choose to take PEP should be advised of the importance of completing the prescribed regimen. Information should be provided about potential drug interactions and drugs that should not be taken with PEP, side effects of prescribed drugs, measures to minimize side effects, and methods of clinical monitoring for toxicity during the follow-up period. HCP should be advised that evaluation of certain symptoms (e.g., rash, fever, back or abdominal pain, pain on urination or blood in the urine, or symptoms of hyperglycemia [e.g., increased thirst or frequent urination]) should not be delayed.

HCP often fail to complete the recommended regimen often because they experience side effects (e.g., nausea or diarrhea). These symptoms often can be managed with antimotility and antiemetic agents or other medications that target specific symptoms without changing the regimen. In other situations, modifying the dose interval (i.e., administering a lower dose of drug more frequently throughout the day, as recommended by the manufacturer) might facilitate adherence to the regimen. Serious adverse events** should be reported to the U.S. Food and Drug Administration's (FDA's) MedWatch program.

** Defined by FDA as follows: "Any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition."

Although recommendations for follow-up testing, monitoring, and counseling of exposed HCP are unchanged from those published previously, greater emphasis is needed on improving follow-up care provided to exposed HCP (see below). This might result in increased adherence to HIV PEP regimens, better management of associated symptoms with ancillary medications or regimen changes, improved detection of serious adverse effects, and serologic testing among a larger proportion of exposed personnel to determine if infection is transmitted after occupational exposures. Closer follow-up should in turn reassure HCP who become anxious after these events. The psychologic impact on HCP of needlesticks or exposure to blood or body fluid should not be underestimated. Providing HCP with

psychologic counseling should be an essential component of the management and care of exposed HCP.

Follow-up of HCP Exposed to Known or Suspected HIV-positive Sources

- Exposed HCP should be advised to use precautions (e.g., avoid blood or tissue donations, breastfeeding, or pregnancy) to prevent secondary transmission, especially during the first 6-12 weeks postexposure.
- For exposures for which PEP is prescribed, HCP should be informed regarding
 - Possible drug toxicities and the need for monitoring
 - Possible drug interactions
 - The need for adherence to PEP regimens
- Consider reevaluation of exposed HCP 72 hours postexposure, especially after additional information about the exposure or source person becomes available.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effective management of occupational exposure to human immunodeficiency virus (HIV), including appropriate implementation and selection of postexposure prophylaxis

POTENTIAL HARMS

- Common symptoms reported by health care personnel receiving postexposure prophylaxis (PEP) included nausea, malaise, and fatigue.
- Development of resistance to antiretroviral agents
- See the Appendix to the original guideline document for information about basic and expanded PEP regimens, including disadvantages of each. See Table 3 in the original guideline document for primary side effects and toxicities associated with antiretroviral agents. See Tables 4 and 5 in the original guideline document for potential drug-drug interactions.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Information included in these recommendations may not represent U.S. Food and Drug Administration approval or approved labeling for the particular product or indications in question. Specifically, the terms "safe" and "effective" may not be synonymous with the Food and Drug Administration-defined legal standards for product approval.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED QUALITY TOOLS

- AIDSinfo's Drug Database for Palm PDAs
- AIDSInfo Drug Database
- A Pocket Guide to Adult HIV/AIDS Treatment: Companion to A Guide to Primary Care of People with HIV/AIDS August 2004 Edition

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Panlilio AL, Cardo DM, Grohskopf LA, Heneine W, Ross CS. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. MMWR Recomm Rep 2005 Sep 30;54(RR-9):1-17. PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 May 15 (updated 2005 Sep 30)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.] Food and Drug Administration (U.S.) - Federal Government Agency [U.S.] Health Resources and Services Administration - Federal Government Agency [U.S.]

National Institutes of Health (U.S.) - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUI DELI NE COMMITTEE

Public Health Service (PHS) interagency working group comprising representatives of the Centers for Disease Control, the Food and Drug Administration, the Health Resources and Services Administration, and the National Institutes of Health.

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Prepared by: Adelisa L. Panlilio, MD, Division of Healthcare Quality Promotion, National Center for Infectious Diseases; Denise M. Cardo, MD, Division of Healthcare Quality Promotion, National Center for Infectious Diseases; Lisa A. Grohskopf, MD, Division of HIV/AIDS Prevention, National Center for HHIV, STD, and TB Prevention; Walid Heneine, PhD, Division of HIV/AIDS Prevention, National Center for HHIV, STD, and TB Prevention; Clara Sue Ross, MD, Division of Surveillance, Hazard Evaluations, and Field Studies, National Institute for Occupational Health

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUI DELI NE STATUS

This is the current release of the guideline.

This guideline is a partial update of a previous guideline: <u>Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis</u>. MMWR Recomm Rep 2001 Jun 29;50(RR-11):1-52. The recommendations contained in the 2005 version of this guideline update recommendations pertaining to the management of occupational HIV exposure. Recommendations for the management of occupational exposure to hepatitis B and hepatitis C viruses contained in the previous guideline are still considered to be current.

Additional status information regarding this guideline is available from the <u>AIDSinfo Web site</u>, telephone (800) 448-0440, fax (301) 519-6616; TTY (888) 480-3739.

GUIDELINE AVAILABILITY

Electronic copies: Available from the AIDSinfo Web site.

The following HTML files are also available from the AIDSinfo Web site:

- <u>APPENDIX A</u>. Practice Recommendations for Health-Care Facilities Implementing the U.S. Public Health Service Guidelines for Management of Occupational Exposures to Bloodborne Pathogens.
- <u>APPENDIX B</u>. Management of Occupational Blood Exposures.
- <u>APPENDIX C</u>. Basic and Expanded HIV Postexposure Prophylaxis Regimens.

Print copies: Available from the Centers for Disease Control and Prevention, National Prevention Information Network (NPIN), P.O. Box 6003, Rockville, MD 20850. Telephone: (800) 458-5231, TTY (800)-243-7012 International number (301)-562-1098. Web site: http://www.cdcnpin.org. Requests for print copies can also be submitted via the AIDSinfo Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis tool for Palm OS* or Pocket PC. The download is available from the AIDSinfo Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 25, 1999. The information was verified by the guideline developer on June 4, 1999. The information was updated by ECRI on September 25, 2001, in response to the June 29, 2001 update. This NGC summary was updated most recently on October 3, 2005 in response to the updated HIV recommendations released September 30, 2005.

COPYRIGHT STATEMENT

No copyright restrictions apply.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse[™] (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx.

NGC, AHRQ, and its contractor ECRI make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2006 National Guideline Clearinghouse

Date Modified: 10/9/2006